

Procedures for Response to Complaints from Outside the NIH

In April 1992, the following process was implemented by the NIH Intramural Research Program Institutional Official, the Deputy Director for Intramural Research (DDIR). The process was developed by the predecessor to the trans-NIH Animal Research Advisory Committee.

The NIH has a responsibility to respond vigorously and expeditiously to all complaints concerning the care and use of animals in the intramural program. While cognizant that allegations must be fully and promptly investigated, and that appropriate measures must be taken to correct any deficiencies as soon as possible, the NIH also recognizes that this process should respect the rights of the individuals involved and should not disrupt legitimate research without due cause.

DDIR has appointed a senior NIH scientist with experience in animal research to function as an ARAC ombudsman to receive, review, and assure an appropriate initial response within hours to complaints concerning the care and use of animals in the intramural program, especially when the complaint may involve more than one IC. Since most complaints originating within the NIH should be properly resolved within the ICs, complaints to the ombudsman would be expected to come mostly from outside the NIH. However, the ombudsman also will be available at the request of the ICs to review unresolved complaints that originate within the ICs. The ombudsman will serve as a member of the ARAC. The DDIR will designate an individual to serve in the ombudsman's absence.

A. The ombudsman will inform the DDIR and the chairperson of the NIH-ARAC about any complaint and decide whether the allegations have sufficient substance to merit an inquiry. If the ombudsman finds that an inquiry is warranted, then he/she will immediately inform the DDIR and assemble a task force, the members to be drawn from outside the IC(s) involved and to include - but not necessarily be limited to - a tenured NIH scientist who is currently active in animal research and a veterinarian from the Office of Animal Care and Use. To meet this requirement, the ombudsman will maintain a list of suitably qualified personnel upon whom he/she can draw at short notice. The ombudsman shall be assigned as an ex officio member of each IC-ACUC and will be representing that/those ACUCs as one of their agents during the immediate on-site assessment by the task force.

B. The ombudsman and his/her task force will make an immediate on-site assessment of the situation solely to determine whether there are any problems of compliance in regard to existing policies and regulations governing the care and use of animals. The task force will be granted ready access to all relevant facilities, individuals and documents. Key personnel who are also expected to be involved during this assessment include the Principal Investigator(s), the Laboratory/Branch Chief(s), the Attending Veterinarian(s), the IC Scientific Director(s), and the Chairperson(s) of the IC-ACUC(s). The ombudsman will discuss his/her preliminary findings with the IC-ACUC(s) and the Scientific

Director(s) who are responsible for taking whatever measures are required to assure immediate and continued compliance so that approved research can proceed. These measures may include temporary monitoring or supervision of the research in question. The ombudsman does not usurp the role of the ACUC(s) in the evaluation of concerns or in the actions taken or in the communication of findings and recommendations to the Institutional Official, including the suspension of research in accordance with the authorities vested in the ACUC(s) under PHS Policy. The IC-ACUC(s) involved in the assessment shall proceed, in accordance with PHS Policy and in a timely fashion, with appropriate actions based upon the findings of the assessment. Those actions would include either an IC-ACUC finding that the complaint was unfounded, or the initiation of an investigation to identify further the facts related to the complaint and implementation of corrective actions.

C. The OACU will notify the Office of Communications and the Office of Scientific Affairs of any public relations concerns, and alert the Division of Public Safety to possible security concerns.

D. The ombudsman will, in a timely fashion, submit a written report of all findings and actions to the DDIR, the IC Scientific Director(s), and the NIH-ARAC. The DDIR may choose to conduct further investigation(s) based on the original complaint and the ombudsman's report, either by tasking the IC-ACUC(s) to conduct such investigations (or acknowledging the IC-ACUC investigation(s) already underway) or by assembling an independent investigative team directed by the DDIR's office.

E. In addition to the actions described above for handling complaints or allegations received from outside the NIH, NIH staff members shall be guided by the DDIR's August 22, 2001 memorandum which delineates the procedures to be followed for handling animal welfare concerns within the NIH intramural program.

Attachment - DDIR memorandum, dated August 22, 2001.

Approved by the DDIR, April 23, 1992.

Readopted by the NIH-ARAC, May 8, 1996.

Revised and recommended by the NIH-ARAC, April 9, 1997.

Reapproved by the DDIR, April 9, 1997.

Revised and recommended by the NIH-ARAC - May 28, 1997.

Approved by the DDIR, May 30, 1997.

Revised - November 10, 1998.

Revised - November 14, 2001